REMARKS

Claims

Claims 1-7, 9-10, 12-16, and 21 are currently under examination with claims 18-20 and 22 withdrawn from consideration due to restriction/election and claims 8, 11 and 17 cancelled without prejudice or disclaimer.

Allowability

On the basis of the contentions raised in the open Office Action, it is respectfully submitted that the subject matter of claims 4 and 5 is free of prior art and further satisfies the statutory requirements under §101 and §112. The Examiner is courteously requested to indicate these claims as "allowable."

Claim amendments

The claims have been amended to use language in accordance with conventional US practice.

Support for amended claim 20 can be found throughout the instant specification as originally filed. See, for example, the paragraph bridging pages 22 and 23. The Examiner is also requested to review the paragraph bridging pages 15 and 16 of the instant specification. See, page 18, lines 10-13 for the definition of the terms m and n as recited in amended claim 20.

Claim 13 has been amended, rendering the objection of said claim moot.

It is respectfully submitted that the claim amendments do not raise new matter.

Restriction

The restriction of claim 20 and its dependent claim 22 is traversed insofar as it is courteously submitted that the subject matter of these claims is drawn to preferred embodiments of the compound of Formula I, which the PTO has agreed to examine on the merits. See, for example, the disclosure contained in the paragraphs bridging page 19, line 14 to page 24, line 17 of the specification, as originally filed. See also, Applicants' instant claim 3 and the newly added claim 21, both of which have been examined on the merits. Withdrawal of the restriction requirement and examination of these claims on the merit is respectfully requested.

The alleged requirement that Applicants "should amend the claims to read on the

elected subject matter" is respectfully traversed since such is not required. Withdrawal of the objection is courteously requested.

A petition against the restriction requirement will be duly filed in a separate paper.

Rejections under 35 U.S.C. §103(a)

The PTO's allegation that the subject matter of claims 1-3, 6, 7, 12-16 are rendered obvious by Peglion's (US 6,399,616) pyridine compounds is respectfully traversed.

The rejection rests on the contention that the difference between Peglion's compound of Formula I and the compounds of the instant invention is "a methyl versus a hydrogen atom" in the substituents R^2, R^3, R^4, and R^5. The Office Action further alleges that the scope of the compounds encompassed in Applicants' claims is rendered obvious by Peglion's disclosure of "structurally and functionally similar" pyridine compounds. Applicants courteously disagree with this contention.

It is clear that this contention, which constitutes the underlying rationale for the obviousness rejection, is rather misplaced. The minimal difference between Peglion's compound and the compounds of the instant invention is not a "methyl" substitutent at R^2, R^3, R^4, and R^5, as alleged by the Examiner at page 6, 2nd paragraph of the open Office Action. The cited reference fails to render the claims obvious because nothing motivates a skilled worker to choose the disclosed substituent at R^2, R^3, R^4, and/or R^5 and combine it with precisely a compound meeting the other requirements of the claims, especially since the details and examples of the reference would point particularly to other types of compounds. Without such motivation, there can be no obviousness. *In re Baird*, 16 F.2d 380 (Fed.Cir. 1994). Moreover, Peglion only recites pyridyl or pyridinyl compounds that are optionally annellated by M. See, Peglion's compound of Formula I in the ABSTRACT section of the cited reference. Insofar as Applicants' preferred compounds no longer recite such derivatives, it is respectfully submitted that the compounds of the instant invention are structurally unobvious over Peglion. See, claims 20-22, which exclude such compounds.

Accordingly, withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. §112, first paragraph

Claims 9–11 and 12–15 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking a written description. Claims 9-16 stand rejected under the same section for allegedly being non-enabled. Applicants respectfully traverse these rejections.

Written Description

At page 8, the Office Action alleges that "method of modulating does not recite a substantial utility." Applicants courteously disagree with this contention. The ability of the compounds to ameliorate and/or antagonize the function of the 5HT receptor is expressly described in the specification. See, page 5, lines 20-24. However, in reference to the activity of the compounds of the instant invention against the claimed bio-molecules (i.e., excitatory amino acids) the claims have been amended to recite an inhibitory activity. Support for the amendment can be found, for example, at page 20, lines 19-21 of the instant specification, as originally filed.

The contention that the "claims seek to treat all or any 5HT-mediated disease without sufficient support in the specification" is respectfully traversed. Applicants' specification expressly teaches that substituted indole compounds, such as compounds of Formula I, serve as anti-psychotic agents because of their ability to inhibit important regulators of the 5HT receptor pharmacology (for example, 5HT agonistic and 5HT reuptake inhibitory activity). See, page 6, lines 15–25. Rationale for the use of the compounds of the instant invention in the treatment of diseases is also provided. See, the paragraph bridging pages 5 and 6 and the paragraph bridging pages 6 and 7 of the specification, as originally filed. The specification provides literature references which discuss techniques for the assessment of the claimed inhibitory activity *in vitro* and its correlation with *in vivo* pharmacology. See, the entire disclosure contained in the paragraphs bridging page 7, line 29 to page 9, line 11 of the instant specification. A skilled artisan, in view of the detailed disclosure contained in Applicants' own specification and the reference publications cited therein, would readily understand that the compounds of the instant invention are useful for the claimed purposes.

The biology of "5HT mediated disorders" is a mature field inasmuch as the major effectors (i.e., neurotransmitters) and the receptors (for example, 5HT/NMDA receptor isoforms) were known to a skilled artisan well before the filing date of the instant

application. In this regard, Applicants' own specification and the references cited therein expressly disclose the centrality of 5HT receptor pharmacology in the etilogy of several neurological disorders and further provide guidance on the utility of 5HT receptor agonist/5HT reuptake inhibition in the treatment of such conditions. The discipline on which Applicants' instant invention is based was therefore mature prior to the filing of the instant application. For example, a search in PUBMED with the term "5HT mediated" reveals nearly 20 publications prior to the earliest priority date of the instant application. See, enclosed Exhibit A. Nearly twenty publications were identified with the search term "serotonin mediated" disorder OR "serotonin mediated" disease. See, enclosed Exhibit B.

A specification need not disclose, and preferably omits, what is well known to those skilled in the art (for example, with respect to the anti-psychotic activity of the claimed compounds). See, e.g., *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987). See, also, MPEP §2164.05(a). Indeed, the Federal Circuit found that an application, which failed to disclose the amino acid sequence of a claimed protein, was not deficient in the written description requirement, despite the fact that the undisclosed sequence was an essential part of the protein's description. See, *Capon v. Eshhar v. Dudas*, (Fed. Cir. 2005) 418 F.3d 1349, 76 U.S.P.Q.2d 1078. Likewise, in the instant application, the specification need not provide expressed guidance with respect to the correlation between 5HT receptor activity on and the treatment of the neurological diseases. This correlation was conventionally appreciated in the art before the application was filed. The Examiner's contention regarding lack of a connection between the two is rebutted by the detailed disclosure contained in the specification and a skilled worker's sophisticated knowledge of the field in which the instant application is based.

It is therefore courteously submitted that Applicants' claims in the current form, with adequate support from the specification and the references cited therein, fully comply with the statutory requirements under 35 U.S.C. § 112, first paragraph, as specified in the PTO's own guidelines. Withdrawal of the rejection is respectfully requested.

Enablement

At the outset, it is courteously submitted that Applicants' specification provides express guidance with respect to the structure of the representative compounds having 5HT agonist/5HT reuptake inhibitory activity and the utilization of such compounds in the treatment of neurological disorders. See, page 5, lines 20-24. Methods for making such compounds are also described. See, the entirety of the disclosure contained in the Examples at page 68 of the instant specification. The Examiner is courteously requested to review the detailed disclosure relating to these compounds and withdraw the pending enablement rejection based on the alleged lack of working examples.

It is by now well-settled law that the burden is on the PTO to present evidence of reasons to doubt the statements of enablement presented in an Applicant's disclosure. See, e.g., *In re Marzocchi*, 439 F.2d 220, 169 U.S.P.Q. 367 (CCPA 1971). The disclosure must be taken as in compliance with the enablement requirement of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein. See *Marzocchi*, supra. As clearly and succinctly stated by the court in *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971):

> As a matter of Patent Office practice, then a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented **must** be taken in compliance with the enabling requirement of the first paragraph of §112, **unless** there is reason to doubt the objective truth of statements contained therein relied on for enabling support. (emphasis in original)

See also, for example, *In re Brana, 51 F.3d 1560,* 34 USPQ2d 1436 (Fed. Cir. 1995), and *Fiers v. Revel, 984 F.2d 1164,* 24 USPQ2d 1601 (Fed. Cir. 1993). Furthermore, as stated in *Marzocchi*, at 370, the PTO must have adequate support (evidence or reasoning) for its challenge to the credibility of applicants' statements of utility. See also *In re Bundy*, 209 USPQ 48 (CPA 1981). Thus, in the absence of evidence which demonstrates otherwise, the claims must be taken to satisfy the requirements of 35 U.S.C. §112, first paragraph. Here, the focus is on the inhibition of 5HT reuptake and/or mediation of 5HT agonist activity by the compound(s) of the instant invention. The rationale for the use of the claimed compounds is clearly described in the specification by the way of scientific references and experimental data.

For example, it is expressly taught that compounds of the instant invention are well-tolerated and that they are useful as antipsychotics, neuroleptics, antidepressants, anxiolytics and/or antihypertonics. It is further taught that the indole compounds of the instant invention can be utilized for combating depression, strokes, cerebral ischaemia, extrapyramidal motor side effects of neuroleptics and of Parkinson's disease, Alzheimer's disease, amyotrophic lateral sclerosis, brain and spinal cord trauma, obsessive-compulsive disorder, sleeping disorders, tardive dyskinesia, learning disorders, age-related memory disorders, eating disorders, such as bulimia, and/or sexual dysfunctions. See, page 5, lines 21–27.

In light of this detailed disclosure, to assert a lack of enablement the courts have placed the burden on the PTO to show otherwise. It is courteously submitted that the Examiner has not presented any evidence to refute the findings or the conclusions made in the specification or the supporting publications. In addition, no evidence has been presented to support the contention that the claimed compounds could not be used, in a manner that is commensurate with Applicants' claimed invention. Only unsupported allegations and conclusions regarding the "complexity" and "unpredictability" of the "state of the art" are provided to support the contention. These are especially weak in the face of the showing that the field of 5HT pharmacology, up-stream regulators and downstream effectors thereof, including strategies for the pharmacological intervention of diseases/disorders mediated by the deregulated activity of such receptors were all conventionally appreciated in the art well before the filing date of the instant application.

In view of the above remarks, it is respectfully submitted that Applicants' disclosure provides more than sufficient guidance to objectively enable one of ordinary skill in the art to make and use the claimed invention with an effort that is routine within the art. The statute requires nothing more. Withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response to Deposit Account No. 13-3402.

Respectfully submitted,

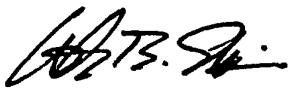

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EXHIBIT A

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